

Sonderhoff & Einsel News Update: China IP Newsletter (August 2017)

Supreme People's Court in China Announces White Paper on Judicial Protection of IP Rights in 2016

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Supreme People's Court in China Announces White Paper on Judicial Protection of IP Rights in 2016

On April 27, 2017, the China Supreme People's Court announced in the "Current Situation of Judicial Protection of IP Rights by the Supreme People's Court (2016)" ("White Paper"), ten court decisions and 50 other representative court decisions regarding the judicial protection of IP rights. The Court's White Paper provides an overview of the current judicial protection of IP rights in China, and hints at how such protection will be apportioned in the future.

Our newsletter focuses on four key Court decisions which deals with the patent production process, product manuals and instructions for maintenance as publication of prior art, disclosure of use and/or effect for chemical product patent applications, and specifications for gene sequence inventions.

1. Patent production process

Eli Lilly and Company vs Jiangsu Huada Chemical Group Co.,Ltd

Key points of the Supreme People's Court's decision:

- In a dispute with respect to a patented production process of a pharmaceutical product, the production process of the accused product which has been registered at Pharmaceutical Product Control Division (CFDA) is acknowledged to be the actual production process being used as long as there is confirmation.
- Should such a process be proven to be different from the actual production process, sufficient research as to where the relevant technology with respect to the accused product came from, and of production regulations, records of batch production, registration documents or the like, and the actual production process of the accused pharmaceutical product must be determined in accordance with the relevant law.
- Complicated technologies in such a production process can be clarified by asking the opinions of experts such as technical researchers, committees, juridical appraisers and experts in the corresponding technologies.

Our comment:

In China, there are still quite a few patent infringement suits with respect to production processes. In a dispute regarding patent infringement concerning a production process of a novel product, the accused party needs to prove that the process he or she is using differs from the patented production process.

What is important in this case is the fact that the Court resolved the dispute by appointing a technology investigator for the first time since the establishment of the technology investigator system in 2014 and had him explain the technical difficulties which were under the examination. Technology investigators in China are supporting staff in court cases and have no authority to give decisions. Their role is to provide the judges with advice on technical issues of cases based on their technical knowledge about chemistry, mechanical and electrical technology or the like, and

cooperate with the judges in response to requests to clarify the technical issues in question. It is expected that the technology investigator system will also be actively utilized in the future for more complicated cases.

2. Product manuals and instructions for maintenance as publication of prior art

ThyssenKrupp Airport Systems, S.A. vs China International Marine Containers (Group) Company Ltd.

Key points of the Supreme People's Court's decision:

- Product manuals and instructions for maintenance are provided to users when products are sold to them and made available to the public. In addition, the users and people who purchase the product do not have any confidentiality obligations with respect to the product manuals and instructions for maintenance. Therefore, such manuals and instructions would be considered publications disclosing the prior art as set forth in the Patent Law.
- The time at which the manuals and instructions are provided to the users is deemed to be the publication date/time of the technical solution.

Our comment:

The main issue of this dispute was whether the defence of the prior art asserted by ThyssenKrupp Airport Systems would be accepted. The Court held that product manuals and instructions for maintenance which disclose technical contents, i.e. the prior art, are independently existing media. They are available to the public and the time of their publication can be clearly indicated, which is consistent with publication under Chinese Patent Law. The Guidelines for Patent Examination also provides additional insight into the definition of a publication: "Publication...can be various printed or typed paper documents, such as patent documents, scientific and technological magazines and books, academic theses, specialized documents, textbooks, technical manuals, officially published proceedings or technical reports, newspapers, sample books, product catalogues, advertisement brochures, etc. They can also be audio or video materials made by electric, optic, magnetic, or photographic means, such as microfiches, films, negative films, videotapes, tapes, gramophone records, CD-ROMs, etc. Furthermore, they can be materials in other forms, such as those on the Internet or in other online databases."

3. Disclosure of use and/or effect for chemical product patent applications

Mitsubishi Tanabe Pharma Corporation vs Patent Reexamination Board of SIPO

Key points of the Supreme People's Court's decision:

- In the case of a chemical product invention, the use and/or effect of a chemical product must be disclosed in the specification of the patent application. If the chemical product is of the nature that a person skilled in the art cannot predict the use and/or effect based on the state of the art, the qualitative or quantitative data showing that the technical solution of the invention achieves the use and/or the expected effects has to be described in the specification.

Our comment:

One of the main issues of this dispute, whether the invention of a novel compound was sufficiently disclosed, depends on whether at least one application/use of such an invention or an effect achieved by the invention was disclosed in the specification. Since it is quite difficult to predict whether an invention of a novel compound can be implemented and how it can be used or what kind of effects can be achieved, experimental data are often used to confirm the above. Also, the Guidelines for Patent Examination states: "As for a chemical product invention, the use and/or its technical effect of the product must be completely disclosed. Even if the structure of the compound has been confirmed for the first time, at least one use of the compound must be described."

Accordingly, when a specification is drafted, descriptions of qualitative as well as quantitative data showing the use/application and/or the expected effects to be achieved should lead to less disputes over the insufficiency of disclosure. Also, according to the Guidelines for Patent Examination as of April 1, 2017, a new provision was introduced where examiners should examine experimental data submitted as a supplement after the filing date. The effects shown in the experiments which are to be proven by this supplementary experiment report need to be based on the disclosures in the patent application. It is expected that for the patent practice in China, the insufficiency of disclosures in the chemistry field can be resolved by supplementary experiment reports which are based on the disclosures in the patent application.

4. Specifications for gene sequence inventions

Patent Reexamination Board of SIPO & Novozymes vs Jiangsu Boli Bioproducts Co., Ltd.

Key points of the Supreme People's Court's decision:

- To determine whether the claimed gene sequence for which patent protection is sought is supported by the specification, it is necessary to consider the limiting influence of the technical features such as homology, and the origin and function of the claimed gene sequence. When the gene sequence is significantly limited by these technical features and can achieve the aim of the invention based on the content disclosed in the specification, and the expected effects can therefore be achieved, it is likely that the claimed gene sequence will be supported by the specification.

Our comment:

For gene sequence inventions, how the invention can be specified in a sensible manner in the claims is a difficult question to answer. In past practice, applicants used to specify the invention by "homogeny + function" to obtain a broad scope of protection. However, this method of specifying the invention was often rejected in patent prosecution because its scope of protection was too broad, the support in the specification was not sufficient, etc. Also, since 2007, this method was also used as an invalidation reason in invalidation trials since 2007. As a result, only those specific gene sequences that were mentioned in the working examples could be protected in many cases.

Against such a background, the Court decided that the claimed invention in question was supported by the specification because the scope of protection had been limited to a very narrow enzyme by specifying it with a homogeneity of 99% or more, derivation from specific species, and glucoamylase activity. In other words, the Court gave a clear answer regarding whether a claimed invention of gene sequences is limited by its homogeneity, origin and function, and therefore is supported by its specification, and also regarding the criteria for the approval of an invention which is specified by gene/amino acid sequences. Therefore, inventions specified in their claims by "significantly high homogeneity + function + origin" are likely to be supported by the specification, but inventions specified in the claims by two elements such as "function + homogeneity" are unlikely to meet the support requirements.

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